



UNITED STATES ENVIRONMENTAL
PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

October 1, 2020

Subject: Technical Screen for Biocide ADBAC 80 (Reg No 90924-RT)

PC Code(s): 069105	DP Barcode(s)/No(s): 458189
Decision No.: 562661	Registration Number (s): 90924-RT
Regulatory Action: Technical Screen	CAS No(s): 68424-85-1
MRID: 51027506	

From:

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Judy Facey, Ph.D., Risk Assessment Process Leader

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Risk Assessment Science Support Branch (RASSB)

Antimicrobials Division (AD) (7510P)

Thru:

Melissa Panger, Ph.D., Branch Chief *Melissa Panger*

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Risk Assessment Science Support Branch (RASSB)

Antimicrobials Division (AD) (7510P)

To:

Karen Leavy Munk, Product Manager

John Hebert, Branch Chief

Regulatory Management Branch I

Antimicrobials Division (7510P)

The Agency has conducted a technical screen for the proposed new Alkyl Dimethyl Benzyl Ammonium Chloride Manufacturing Use Product (MUP), tradename Biocide ABDAC 80 (EPA Reg. No. 90924- RT) by Nalco Champion. This product is intended for formulating into antimicrobial products for use in/on oil and gas production applications (such as drilling, completion, and workover fluids, packer fluids, fracturing fluids, water floods and enhanced oil recovery fluids, injection waste fluids, oil and gas water storage and transmission systems, hydrotesting, pipeline pigging and scraping operations, hydrocarbon production, storage, and transmission systems), service water and auxiliary systems, industrial processes and water systems, air-washer and industrial scrubbing systems, once-through and recirculating industrial/commercial cooling water systems, industrial wastewater systems. This product may also be used to formulate products for specific use(s) not listed on this MUP label if the formulator, user group, or grower has complied with the U.S. EPA data submission requirements

regarding the support of such use(s). The proposed product label (dated February 18, 2020) is attached at the end of this memorandum. The purpose of this technical screen is to determine whether the label and other information submitted with the application are sufficient to allow the assessment of human toxicology, occupational and residential exposure, ecological toxicity, and environmental fate as enumerated in 40 C.F.R. part 158 subpart W.

The application as submitted **fails** the technical screen in that the registrant did not properly cite how it plans to address the required immunotoxicity study. In addition, the Agency does not have the cited CITE-ALL for the 835.1230/1240 leaching and adsorption/desorption studies, and the 835.1110 ASSI study for ADBAC. If a data waiver is submitted for the immunotoxicity study and the cited 835.1230/1240 leaching and adsorption/desorption studies, and the 835.1110 ASSI study for ADBAC are submitted to the Agency, all mammalian toxicology and ecological fate and effects data will be satisfied, and the tech screen will pass.

Mammalian Toxicology (Fails the Screen)

The registrant has cited various mammalian toxicology data and Agency Waivers for the mammalian data in support of the proposed uses of the product. The following data were cited by the registrant:

Table 1. Mammalian Toxicology data Required for the Proposed Uses of Biocide ADBAC
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Toxicology Data Requirements		Nalco Champion Citations
870.1100	Acute Oral Toxicity: Rat	45109204 (Old); RED
870.1200	Acute Dermal Toxicity	45109202 (Old); RED
870.1300	Acute Inhalation Toxicity: Rat	44885201 (Old); RED
870.2400	Primary Eye Irritation: Rabbit	51027503 (Waiver Submitted)
870.2500	Primary Dermal Irritation	45109201 (Old); RED
870.2600	Dermal Sensitization	45109203 (Old); RED
870..2600	Acute Neurotoxicity	N.R.
870.3100	90-Day Oral Toxicity: Rodent	N.R.
870.3150	90-Day Oral Toxicity: Nonrodent	N.R.
870.3250	21/28-Day Dermal Toxicity	N.R.
870.3250	90-Day Dermal Toxicity	N.R.
870.3465	90-Day Inhalation Toxicity: Rat	N.R. 51027506 (Waiver Submitted)
870.6200	90-Day Neurotoxicity: Rat	N.R.
870.4100	Chronic Oral Toxicity: Rodent	N.R.
870.4200	Carcinogenicity: Rat and Mouse	N.R.
870.3700	Prenatal Developmental Toxicity: Rat and Rabbit	42392801 (Old); RED
870.3800	Reproduction and Fertility Effects	41385001 (Old); RED
870.6300	Developmental neurotoxicity	N.R.
870.5100	Reverse Mutation Assay	41012701 (Old); RED
870.5300	In Vitro Mammalian Gene Mutation	40311101 (Old); RED
870.5375		
870.5385	In Vitro Cytogenetics	42290201 (Old); RED
870.5395		
870.7485	Metabolism and pharmacokinetics	N.R.
870.7200	Companion animal safety	N.R.
870.7600	Dermal penetration	N.R.
870.7800	Immunotoxicity	MISSING

N.R. is not required by the 158 W guidelines.

The registrant has cited data/has made waiver requests for the toxicology data requirements. The acceptability of the inhalation data waiver will be determined during the risk assessment for the product. The registrant did not indicate how it plans to address the immunotoxicity study required. No study or study waiver was submitted. The submission fails the screen for mammalian toxicology.

Occupational and Residential Exposure (Passes the Screen)

The registrant has cited occupational and residential exposure data in support of the proposed uses of the product. The following data were cited by the registrant:

Table 2. Occupational and Residential Exposure Data Required for the Proposed Uses of Biocide ADBAC 80

Occupational and Residential Exposure Data Requirements		Nalco Champion Citations
875.1100	Dermal outdoor exposure	AEATF II
875.1200	Dermal indoor exposure	AEATF II ^{1,2}
875.1300	Inhalation outdoor exposure	AEATF II
875.1400	Inhalation indoor exposure	AEATF II
875.1500	Biological Monitoring	N.R.
875.1600	Data reporting	AEATF II
875.1700	Product use information	See label
875.2100	Dislodgeable foliar residue and turf transferable residues	N.A.
875.2200	Soil residue dissipation	N.A.
875.2300	Indoor surface residue dissipation	N.R.
875.2400	Dermal exposure	N.R.
875.2500	Inhalation exposure	N.R.
875.2600	Biological monitoring	N.R.
875.2700	Product use information	See label
875.2800	Description of human activity	AEATF II
875.2900	Data reporting and calculations	N.R.

The registrant has cited data for the occupational and residential exposure data requirements. The submission passes the screen for occupational and residential exposure.

Ecological Fate and Effects (Fails the Screen)

The registrant has cited various old ecological effects data for fate and effects in support of the proposed uses of the product. The following data were cited by the registrant:

Table 3. Ecological Effects Data Required for the Proposed Uses of Biocide ADBAC 80

Ecological Effects Data Requirements Mentioned in the Data Matrix		Nalco Champion Citations
850.1010	Acute freshwater invertebrate toxicity	41947203 (old); RED
850.1075	Acute freshwater fish toxicity	41947201 (old); RED
850.1025/1035/1045/1055	Acute estuarine and marine organisms toxicity	42479502; 42479501 (old) RED
850.1300	Aquatic invertebrate life-cycle (freshwater)	CITE-ALL
850.1350	Aquatic invertebrate life-cycle (saltwater)	N.R.
850.1400	Fish early life stage (freshwater)	42302102 (old); RED
850.1500	Fish life cycle	N.R.

¹ Nalco Champion is a member in good standing with the Antimicrobial Task Force II (AEATF II). All Occupational Exposure will be addressed via one of their working groups.

² Letters of good standing was attached (submitted) for AEATF II.

Ecological Effects Data Requirements Mentioned in the Data Matrix		Nalco Champion Citations
850.1710/1730	Aquatic organisms, bioavailability, biomagnification, toxicity tests	N.R.
850.1735	Whole sediment: acute freshwater invertebrates	N.R.
850.1740	Whole sediment: acute marine invertebrates	N.R.
850.1850/1950	Simulated or actual field testing for aquatic organisms	N.R.
850.2100	Acute avian oral toxicity	42885901 (old); RED
850.2200	Avian dietary toxicity	N.R.
850.2300	Avian reproduction	N.R.
850.3020	Honey bee acute contact toxicity	N.R.
850.3030	Toxicity of residues to honeybees	N.R.
850.4225	Seedling emergence, Tier II	N.R.
850.4250	Vegetative vigor, Tier II	N.R.
850.4300	Terrestrial field	N.R.
850.4400	Aquatic plant growth (aquatic vascular plant), Tier II	CITE-ALL
850.4450	Aquatic field	N.R.
850.5400	Aquatic plant growth (algal), Tier II	CITE- ALL

Table 4. Environmental Fate Data Required for the Proposed Uses of Biocide ADBAC 80

Environmental Fate Data Requirements Mentioned in the Data Matrix		Nalco Champion Citations
835.1110	Activated sludge sorption isotherm	CITE-ALL
835.1230/1240	Leaching and adsorption/desorption	CITE-ALL
835.2120	Hydrolysis	40835602 (old); RED
835.2240	Photodegradation in water	40835603 (old); RED
835.2410	Photodegradation in soil	N.A.
835.3110	Ready biodegradability	N.R.
835.3220	Porous pot study	N.R.
835.3240	Simulation test - aerobic sewage treatment: A. Activated sludge units	N.R.
835.3280	Simulation tests to assess biodegradability of chemicals discharged to wastewater	N.R.
835.4100	Aerobic soil metabolism	N.R.
835.4200	Anaerobic soil metabolism	N.A.
835.4300	Aerobic aquatic metabolism	40835604 (old); RED
835.4400	Anaerobic aquatic metabolism	41105501 (old); RED
835.6200	Aquatic (sediment)	N.R.
None	Monitoring of representative U.S. waters	Waived RR
None	Special leaching	N.A.
850.6800	Activated sludge respiration inhibition test OECD 209	CITE-ALL

N.A. "Not Applicable"

The registrant has cited CITE-ALL for the 850.6800 ASRI study. The Agency at this time has not completed its review of the 850.6800 ASRI study for ADBAC. The results of the ASRI study determine which future studies may be required. The potential subsequent study requirements have not been addressed by the registrant citing the studies for 835.4300 and 835.4400.

If the ASRI test EC^{50} is equal to or less than 20 mg/L, the registrant must choose to conduct at least one of the following three guidelines: 835.3280 Simulation Test biodegradability in wastewater, 835.3220 Porous Pot, 835.3240 Simulation Test - aerobic sewage treatment. If the ASRI test EC^{50} is greater than 20 mg/L, the registrant must choose to conduct at least one of the following guidelines: 835.3110 Ready Biodegradability, 835.3280 Simulation Test biodegradability in wastewater, 835.3220 Porous Pot, 835.3240 Simulation Test - aerobic

sewage treatment. No waiver or studies have been submitted for these studies, instead they are designated as not required. Given that there is no ASRI study, the potential subsequent study requirement must be addressed.

The registrant has cited CITE-ALL for the 835.1230/1240 leaching and adsorption/desorption studies, and the 835.1110 ASSI study. The Agency does not have these studies for ADBAC at this time.

Because of this, the submission **fails** the screen for fate and effects data.

References:

US EPA (2006) Reregistration Eligibility Decision for Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC). Docket: EPA-HQ-OPP-2006-0339. Signed Aug 3, 2006.

US EPA (2019). MRID 51027503. Primary Eye Irritation Study – Waiver Request of Requirements for Testing. DP458189.

US EPA (2020). Biocide ADBAD 80 Data Matrix with Submitter List Confidential. DP458189. Signed Feb 18, 2020.

US EPA (2020). Biocide ADBAD 80 Product Label. DP458189. Signed Feb 18, 2020.

US EPA (2020). MRID 51027506. Subchronic Inhalation Toxicity – Waiver Request of Requirements for Testing. DP458189.

Master Label Dated February 18, 2020

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BIOCIDE ADBAC 80

For Manufacturing Use. For Formulating into Antimicrobial Products for Uses Indicated on the Label.

Active Ingredient:

Alkyl* Dimethyl Benzyl Ammonium Chloride..... 80.0%

*(50% C14, 40% C12, 10% C16)

Other Ingredients..... 20.0%

TOTAL..... 100.0%

Nalco Champion

11177 S. Stadium Drive

Sugar Land, TX 77478

EPA Reg. No. 90924-XXX

EPA Est. No.

Net Contents: Gallons

Net Weight: Pounds

KEEP OUT OF REACH OF CHILDREN

DANGER

FIRST AID

IF IN EYES: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye.

IF ON SKIN: Take off contaminated clothing. Rinse skin immediately with plenty of water for 15-20 minutes.

IF SWALLOWED: Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by a poison control center or doctor. Do not give anything by mouth to an unconscious person. Call a poison control center or doctor immediately for treatment advice.

IF INHALED: Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably mouth-to-mouth if possible.

FOR EMERGENCY MEDICAL INFORMATION, CALL TOLL-FREE 1-800-424-9300

Have the SDS and, if available, the product container or label with you when calling a poison control center (or a doctor) or going for treatment. BIOCIDE ADBAC 80 February 18, 2020

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NOTE TO PHYSICIAN: Probable mucosal damage may contraindicate the use of gastric lavage.
{SEE SIDE PANEL FOR ADDITIONAL PRECAUTIONARY STATEMENTS}

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

This product is for formulating into antimicrobial products only. Formulators using this product are responsible for obtaining EPA registration of their formulated product and for providing any data needed to secure and maintain their product registration.

For formulating into antimicrobial products for use in/on oil and gas production applications (such as drilling, completion, and workover fluids, packer fluids, fracturing fluids, water floods and enhanced oil recovery fluids, injection waste fluids, oil and gas water storage and transmission systems, hydrotesting, pipeline pigging and scraping operations, hydrocarbon production, storage, and transmission systems), service water and auxiliary systems, industrial processes and water systems, air-washer and industrial scrubbing systems, once-through and recirculating industrial/commercial cooling water systems, industrial wastewater systems. This product may also be used to formulate products for specific use(s) not listed on this MUP label if the formulator, user group, or grower has complied with the U.S. EPA data submission requirements regarding the support of such use(s).

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

PESTICIDE STORAGE: Open dumping is prohibited. Store only in original container in areas inaccessible to children or persons unfamiliar with its proper use. Do not store on side.

PESTICIDE DISPOSAL: Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste Representative at the nearest EPA Regional Office for guidance.

CONTAINER HANDLING AND DISPOSAL:

(**Note to Reviewer:** One or more of the following paragraphs for Container Handling will be selected, depending on packaging use/type.)

(For Refillable Containers)

Refillable Container. Refill this container with this product only. Do not reuse this container for any other purpose. Cleaning the container before final disposal is the responsibility of the person disposing of the container. Cleaning before refilling is the responsibility of the refiller. To clean
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the container before final disposal, empty the remaining contents from this container into application equipment or a mix tank. Fill container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times.

(For Non-Refillable Containers ≤ 5 gallons)

Non-Refillable Container. Do not reuse or refill this container. Triple rinse (or equivalent) promptly after emptying. Triple rinse as follows: Fill the container ¼ full with water and recap. Shake for 10 seconds. Drain for 10 seconds after the flow begins to drip. Follow Pesticide Disposal instructions for rinsate disposal. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration. If not triple rinsed, these containers are acute hazardous wastes and must be disposed of in accordance with local, state, and federal regulations.

(For Non-Refillable Containers > 5 gallons but ≤ 100 gallons.)

Non-Refillable Container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Fill the container ¼ full with water. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 30 seconds. Stand the container on its end and tip back and forth several times. Turn the container over onto its other end and tip back and forth several times. Follow Pesticide Disposal instructions for rinsate disposal. Repeat this procedure two more times. Then offer for recycling if available or puncture and dispose of in a sanitary landfill, or by incineration.

(For Non-Refillable Containers > 100 gallons)

Non-Refillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. To clean the container, empty the remaining contents from this container into application equipment or a mix tank. Fill the container about 10 percent full with water. Agitate vigorously or recirculate water with the pump for 2 minutes. Pour or pump rinsate into application equipment or rinsate collection system. Repeat this rinsing procedure two more times. Return to point of sale or offer for recycling if available or reconditioning if appropriate.

Precautionary Statements

Hazards to Humans and Domestic Animals

DANGER. Corrosive. Causes irreversible eye damage and skin burns. May be fatal if inhaled. Harmful if absorbed through skin. Do not breathe vapor or spray mist. Wear a dust/mist filtering respirator. A minimum of a filtering face piece NIOSH approved respirator (TC-84A) with any N filter. Higher level respirators that are NIOSH approved for particulates can also be used. Do not get in eyes, on skin or on clothing. Wear protective eyewear, clothing and gloves (goggles, face shield, safety glasses and rubber gloves). Wash thoroughly with soap and water after BIOCID E ADBAC 80

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handling and before eating, drinking or using tobacco. Remove contaminated clothing and wash before reuse.

ENVIRONMENTAL HAZARDS

This pesticide is toxic to fish. Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

PHYSICAL OR CHEMICAL HAZARDS

Combustible. Do not use or store near heat or open flame. Do not mix with oxidizers, soap, or other anionic materials.

Note: Seller makes no warranty, expressed or implied, concerning the use of this product other than indicated on the label. Buyer assumes all risk and/or handling of this material, when such use and/or handling is contrary to label directions.

Batch/Lot Number:

(Note to EPA Reviewer: Batch/Lot Number may or may not appear on label but will appear on the container.)

Net Contents: As indicated on the label or elsewhere on container